REMARKS

By this amendment, a minor correction has been made to Claim 5 as per the Examiner's objection which noted that a period had inadvertently been left out of the claim. Claims 1-25 are currently pending, and Claims 1-7, 14-16 and 22-24 are currently being examined. For reasons as set forth below, Applicants submit that the Examiner's prior art rejections are respectfully traversed and that this case is in condition for allowance.

In the Official Action, the Examiner had rejected Claims 1-7, 14-16 and 22-24 under 35 U.S.C. §102(e) as being anticipated by Yu et al. U.S. Pat. No. 7,244,833. The Examiner also rejected Claims 1-7, 14-16 and 22-24 under 35 U.S.C. §102(e) as being anticipated by Rosen et al. WO 2001/079442. Finally, the Examiner rejected Claims 22-24 under 35 U.S.C. §102(e) as being anticipated by Nissen et al. U.S. Pat. Publication No. 2002/0004483. These rejections are respectfully traversed for at least the reasons set forth below.

As the Examiner recognizes, the present claims are directed to a fusion polypeptide comprising a human serum albumin fragment or polymer that is attached to a therapeutically active polypeptide in such a manner so as to optimize the half-life of the polypeptide in the bloodstream. As indicated, e.g., in Claims 6 and 7, this optimization includes extending the half-life of the polypeptide when necessary (Claim 6) or reducing the half-life of the polypeptide when necessary (Claim 7). As will be shown below, none of the cited references disclose this type of fusion polypeptide, and thus the present claims are clearly patentable over those references.

The first reference cited by the Examiner, Yu et al., relates to well known fusion proteins using the regular human serum albumin protein, and not fragments or polymers of albumin as in the presently claimed invention. Even further, contrary to the Examiner's position, the Yu reference does not disclose or even remotely suggest using a fusion protein to optimize the half-file of a therapeutic polypeptide. Instead, the Yu reference solely discloses that the fusion proteins will invariably increase the half-life of the fused CPSF, see column 14, lines 18-22 and 27-31. At no point does Yu disclose or remotely suggest any use in optimization as is carried out in Applicants' presently claimed invention. Since the Yu et al. reference does not disclose the fusion polypeptide comprising a fragment or polymer of albumin as claimed in the present invention, nor does it disclose the optimization of half-life as in Applicants' claimed invention, it cannot anticipate the present claims. Accordingly, the Examiner's rejection of the claims on the basis of this reference is respectfully traversed and should be withdrawn.

The second reference cited by the Examiner, Rosen et al., is even further afield and also does not cite or remotely suggest the present claims. In the first place, contrary to the Examiner's position, the Rosen et al. reference does **not** disclose increasing the plasma half life of a fused protein. In fact, this reference is **completely silent** with regard to half-life in the bloodstream. Instead, the reference discloses an extension of **shelf life** of a fused protein, and **not** half-life which is different and unrelated to shelf life. See, e.g., page 3, lines 23-31. Moreover, as with the Yu reference, the Rosen reference does not disclose or remotely suggest any optimizing, which even makes this reference further distinguishable from the present claims.

It is thus clear that the Rosen reference does not disclose use of fusion proteins to affect half-life and thus does not disclose using those proteins to optimize any parameter, much less the half-life of a therapeutic polypeptide which is not even disclosed in the first place. Accordingly, the Examiner's rejection on the basis of the Rosen reference is respectfully traversed and should be withdrawn.

Finally, as indicated above, the Examiner rejected Claims 22-24 on the basis of Nissen US publication 2002/0004483, thus recognizing that Nissen does not disclose the use of a fragment of human serum albumin as in Applicants' other claims. However, the Nissen reference does **not** disclose or remotely suggest the use of a human serum albumin polymer in optimizing the half-file of a therapeutic protein as in the present claims, particularly claims 22-24. In the first place, it is clear that the reference is **not** referring to a polymer of human serum albumin (i.e., two or more albumin molecules) as referred to in the present claims. Instead, as indicated at paragraph 24, page 3, the "polymer" is "formed by covalent linkage of two or more monomers, wherein none of the monomers is an amino acid residue, **except where the polymer is human albumin...**" [Emphasis added]. In other words, the reference is not disclosing a polymer of human serum albumin, it is saying that the human serum albumin is considered a polymer only because it is made up of a chain of amino acid "monomers." This is consistent with the reference to the polymer molecule being "human albumin" in paragraph 124 on page 12. The Nissen reference thus does **not** disclose the use of a polymer of human serum albumin, only that the albumin protein can be used in a fusion protein which was known.

Even further, much as in the previous cited references, the Nissen reference is totally silent with regard to optimizing half-life of a therapeutic protein in the bloodstream. At most, the reference only disclose increasing half-life (see, e.g., paragraphs 12 and 124, and does not disclose or remotely suggest optimizing half-life as is done in Applicants' claimed invention.

Accordingly, the Nissen reference clearly does not disclose an albumin polymer fusion protein as in the present claims, nor does it disclose optimizing half-life as is done in Applicants' claimed invention. Thus, the Examiner's rejection of Claims 22-24 on the basis of this reference is respectfully traversed and should be withdrawn.

In light of the above amendments and arguments, Applicants submit that the outstanding rejections and objections have been traversed, and that the present application is now in condition for immediate allowance. Such action is respectfully requested.

Respectfully submitted,

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